

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
DOCKET NO. 3:12-cv-00213-MOC-DCK

CAMERON MCINTYRE)	
ROMAN ZAK,)	
)	
Plaintiffs,)	
)	
Vs.)	ORDER
)	
SIMON PEDDER)	
L. ARTHUR HEWITT)	
J. NICK RIEHLE)	
CHELSEA THERAPEUTICS)	
INTERNATIONAL, LTD.)	
WILLIAM D. SCHWIETERMAN,)	
)	
Defendants.)	

THIS MATTER is before the court on defendants' Motion to Dismiss Amended Class Action Complaint pursuant to Rule 9(b) and Rule 12(b)(6) (#111) and Request [Motion] for judicial Notice and Notice of Incorporation by Reference (#114). Having considered defendants' motions, plaintiffs' responses, and defendants' replies, the court denies those motions and directs defendants to Answer the Third Amended Class Action Complaint within 21 days, all for the reasons that follow.

FINDINGS AND CONCLUSIONS

I. Background¹

In considering the pending motions, the court has read the Third Amended Class Action

¹ To further consistency, the court has drawn heavily from the factual background authored by the Court of Appeals for the Fourth Circuit in Zak v. Chelsea Therapeutics, Intern., Ltd., 780 F.3d 597 (4th Cir. 2015).

Complaint in a light most favorable to the party resisting dismissal, plaintiff. Under Rule 12(b)(6), this court “accept all factual allegations in the complaint as true,” and “consider[s] the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference.”

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007).

In 2006, Chelsea Therapeutics International, Ltd. (“Chelsea”) sought to gain approval from the Food and Drug Administration (“FDA”) to market the drug NORTHERA as a treatment for symptomatic neurogenic orthostatic hypotension (“NOH”). After determining that there was a “significant unmet need” for a clinically beneficial treatment of symptomatic NOH, the FDA assigned NORTHERA “orphan drug status,” which gave Chelsea seven years of marketing exclusivity and reduced certain time and expense requirements related to clinical trials mandated for FDA approval of the drug.

In order to submit a “new drug application” to the FDA, Chelsea conducted a number of clinical trials with “endpoints” to demonstrate the drug's efficacy and safety. Chelsea conducted four efficacy trials: Studies 301, 302, 303, and 306. The first study to conclude, Study 302, failed to meet its primary endpoint and documents showed that the results of Study 302 “clearly . . . dr[e]w the efficacy of [the drug] into question,” and demonstrated that symptoms worsened for those individuals taking the drug.

Chelsea announced to investors the disappointing results from Study 302, but it petitioned the FDA to modify the endpoint for Study 301, which was then ongoing. In November 2009, Chelsea representatives met with FDA officials, and later informed investors that the FDA had agreed to permit Chelsea to use a different assessment scale for Study 301 than was used in Study

302. The FDA officials also recommended at the November 2009 meeting that Chelsea submit a confirmatory study supporting the new drug application, because of the failed results in Study 302. Based on this additional recommendation, Chelsea announced plans to initiate a new clinical trial, Study 306, which would involve an eight-week treatment period. [REDACTED]

In September 2010, Chelsea announced that Study 301 had concluded. It indicated to investors that such study had successfully met its revised endpoint by showing a statistically significant improvement in participants' symptoms. This study, which employed a treatment period of only one week, was the only efficacy study conducted by Chelsea that met its primary endpoint. Study 303, a longer study, did not meet its endpoint and failed to demonstrate that the drug provided any "duration effect" on symptoms. Likewise, Study 306 was abandoned after an interim analysis indicated that the study would not meet its endpoint.

With only Study 301 reaching its endpoint, Chelsea again met with FDA officials on December 10, 2010, to assess submitting a new drug application based on that study alone. FDA officials again warned Chelsea that a single successful study typically was not sufficient to support approval of a new drug. Chelsea publicly announced, however, that the FDA had "agreed" that Chelsea's new drug application for NORTHERA could be submitted based on data from Study 301 and data from Study 302, which had not met its primary endpoint, without the need for any further efficacy studies.

Chelsea thereafter conducted a conference call held with Chelsea investors, at which Dr. Simon Pedder, Chelsea's President and Chief Executive Officer, described the December 2010 meeting as a "successful outcome" that "reflect[ed] the strength of the data" generated by Chelsea's drug development program, and "mark[ed] a significant step forward for Chelsea." Dr. Pedder

also stated that the FDA officials had clarified “that additional efficacy studies were not required” for a new drug application filing. On the same conference call, Dr. William Schwieterman, Chelsea's Vice President and Chief Medical Officer, represented that after the December 2010 meeting, Chelsea was “very pleased” with the FDA's responses to [redacted] { "pageset": "S2f" } Chelsea's questions about its application and supporting data. After these optimistic statements concerning the December 2010 meeting, Chelsea's stock price rose about 28 percent.

Similarly, in September 2011, Chelsea announced that it had submitted to the FDA its new drug application based on purportedly “robust” efficacy data from Studies 301 and 302. In accordance with the FDA's initial evaluation process for new drug applications, an FDA staff member prepared a briefing document in advance of the meeting of the FDA's Cardiovascular and Renal Drugs Advisory Committee (the advisory committee). The briefing document included the staff members' recommendation against approval of NORTHERA, which recommendation was based in part on Chelsea's failure to demonstrate that the drug had a “durable effect (i.e., more than 4 weeks).” On February 13, 2012, Chelsea issued a press release, which stated that it was in “receipt of [the] briefing document,” and that “several lines of inquiry . . . have emerged as significant components of the benefit-risk analysis of NORTHERA,” including that Chelsea's drug development program “may not adequately establish a durable treatment effect as a result of the short duration of” the clinical trials. [redacted] This release did not, however, disclose that the FDA briefing document had concluded with a recommendation that NORTHERA not be approved. Such press release was made available by Chelsea more than a week before the FDA published its documents, but stated that the advisory committee would review the application on February 23, 2012, and referenced a website address where the FDA briefing document later would

be made available. After the press release, Chelsea's stock price dropped 37.5 percent and dropped again on February 21, 2012, an additional 21 percent when the FDA briefing document was made available.

Despite such setbacks, on February 23, 2012, however, the FDA advisory committee announced its non-binding recommendation in favor of approving NORTHERA as a new drug. Several members of the advisory committee raised the same concerns outlined in the staff briefing document. Although the advisory committee chairperson voted in favor of approving the drug, he nevertheless stated "virtually all [members of the advisory committee] agree that" the failed studies "do not provide confirmatory evidence of benefit. And the primary study, [Study] 301[,] also did not provide evidence regarding the duration of effect in any direct way." On March 28, 2012, the FDA denied the new drug application. The FDA provided its decision in a "complete response letter," stating, among other things, that the FDA required an additional successful study to support "durability of effect."

While having no impact on whether investors were misled, whether the claims have been sufficiently pled, or whether this action should move forward, the court notes that NORTHERA was eventually approved by the FDA to treat NOH on or about February 18, 2014. See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm386311.htm>.

II. Litigation History

A week after the March 28, 2012, announcement by the FDA, plaintiffs filed this action and later filed their Consolidated Class Action Complaint ("Complaint"), asserting violations of Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, 17 C.F.R. § 240.10b-

5 (Rule 10b-5). Plaintiffs are investors who purchased Chelsea stock between November 3, 2008, and March 28, 2012 (the class period), and have asserted a number of claims, including claims including that defendants misled investors to believe that the FDA would approve NORTHERA based on the results of only one successful efficacy study, citing to dozens of allegedly misleading statements or material omissions by the defendants.

In response, the defendants filed their first Motion to Dismiss the Complaint under Rule 12(b)(6), contending that the Complaint failed to show that the defendants made any materially false statements or omissions, and that any such statements or omissions were not made with the required *scienter*. The defendants attached to their motion several exhibits and asked the court to take judicial notice of them. These exhibits included three documents that were filed with the SEC (the “SEC documents”), two of which were SEC “Form 4” reports, filed by Dr. Schwieterman as the “Reporting Person,” showing that while employed as a corporate officer he made two purchases of Chelsea stock during the class period. The third document submitted by the defendants, a “Definitive Proxy Statement” filed with the SEC, listed the amount of Chelsea stock shares held by the company's officers at the end of February 2012, near the end of the class period. The Proxy Statement showed that Dr. Pedder owned 2.8 percent of all shares of Chelsea stock, while other officers owned lesser amounts of Chelsea stock. However, the Proxy Statement did not reflect whether any of these stock holdings had been acquired or sold during the class period.



At a hearing on the first Motion to Dismiss, counsel for the defendants represented that none of the Chelsea officers had sold shares of Chelsea stock during the class period. The defendants argued that the absence of such sales undermined any inference of *scienter* on the part

of the defendants. The plaintiffs objected to the court's consideration of the SEC documents, asserting that the record did not show definitively "whether any individual purchased stock or sold stock during the class period" because there had not been any discovery in the case.

At the conclusion of the hearing, this court took judicial notice of the SEC documents, and granted the defendants' motion to dismiss. Applying the heightened pleading standards of the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u-4(b)(2), this court held that the plaintiffs' securities fraud claims failed because the plaintiffs did not plead allegations sufficient to support a strong inference of *scienter* because: (1) defendants provided many warnings to investors regarding the sufficiency of the new drug application; and (2) when weighing the competing inferences regarding *scienter*, "the most glaring" inference was "the fact that none of the individual defendants sold stock during the class period." (Emphasis in original). This court concluded that the lack of stock sales "tip[ped] the scales in favor of defendant[s'] motion" to dismiss, rendering the plaintiffs' allegations insufficient as a matter of law to establish the required inference of *scienter*.

On appeal from such dismissal, the Court of Appeals for the Fourth Circuit reversed this court's decision on two grounds. First, the appellate court found that this court "erred in taking judicial notice of the challenged documents filed with the SEC, because those documents did not relate to the contents of the complaint." Zak v. Chelsea Therapeutics Int'l, Ltd., 780 F.3d 597, 601 (4th Cir. 2015). The Fourth Circuit noted this was not harmless error, because it played a large role in the court's holding that plaintiffs' *scienter* allegation was insufficient. Id. Second, the appellate court held that "based on the defendants' failure to disclose critical information about the weaknesses of the new drug application, the plaintiffs' allegations were sufficient to support a

strong inference of scienter.” *Id.* The Fourth Circuit noted that its conclusion was limited to the sufficiency of the complaint regarding *scienter* and does not address the sufficiency of the allegations in regard to the remaining elements of the plaintiffs’ claims. *Id.* at 611.

III. Standard of Review: Motion to Dismiss Under Third Amended Class Action Complaint under the PSLRA

Generally, to survive a motion to dismiss, a plaintiff’s allegations must contain substantive elements of a valid claim under some legal theory. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Rather, pleadings must contain sufficient factual information to state a claim that is “plausible on its face,” id., and that “raises a right to relief above the speculative level.” Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). A complaint cannot survive Rule 12(b)(6) review where it contains “naked assertion[s] devoid of further factual enhancement.” Id. at 557. “In considering a motion to dismiss, the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff.” CTI/DC, Inc. v. Selective Ins. Co. of America, 392 F.3d 114, 118 (4th Cir. 2004). Courts are not bound, however, by a plaintiff’s legal conclusions. Randall v. United States, 30 F.3d 518, 522 (4th Cir. 1994), cert. denied, 514 U.S. 1107 (1995). Similarly, the court “need not accept as true unwarranted inferences, unreasonable conclusions, or arguments.” Eastern Shore Markets, Inc. v. J.D. Assocs. Ltd., P’ship, 213 F.3d 175, 180 (4th Cir. 2000).

The standard for pleading changes when a complaint is brought under the Private Securities Litigation Reform Act (“PSLRA”). To plead a claim under PSLRA, a plaintiff must show (1) a material misrepresentation or omission by the defendant; (2) *scienter*; (3) a connection between

the misrepresentation or omission and the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation. See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc., 552 U.S. 148, 157 (2008). The Fourth Circuit has noted that sufficiently pleading these elements is “demanding.” Cozzarelli v. Inspire Pharm. Inc., 549 F.3d 618, 623 (4th Cir. 2008).

IV. Discussion

Defendants’ motions raise essentially two issues for the court. Before reaching the Motion to Dismiss, the court must first determine whether it should grant defendants’ Request [Motion] for Judicial Notice and Notice of Incorporation by Reference (#114). Clearly, the viability of defendants’ motion is dependent on the court taking such notice. Second, the court must determine whether Plaintiff has pleaded a complaint which can survive the heightened PSLRA standard.

A. Incorporating Extrinsic Documents

In considering their Motion to Dismiss, defendants request that the court incorporate two documents by reference into the complaint. The first document in question is the revised FDA Briefing Document for the Cardiovascular Renal Drugs Advisory Committee for NORTHERA from February 23, 2012. Defendant requests the court consider the original version as well, because the revised version Plaintiff incorporated into his complaint omitted a great deal of the original Briefing Document. The second document is the FDA Cardiovascular and Renal Drugs Advisory Committee Meeting Transcript from January 14, 2014. Defendant argues the transcript satisfies Federal Rule of Evidence 201(b), and is therefore judicially noticeable, inasmuch as the fact that the offered statements were made is not subject to reasonable dispute, the transcript is known within the court’s jurisdiction by virtue of being publically available on the FDA’s website,

and that it is coming from the FDA, a source whose accuracy cannot reasonably be questioned. Further, defendants argue that the transcript provides context for an issue that is integral to plaintiffs' Third Amended Class Action Complaint, to wit, that the company failed to provide the FDA with site-specific data.

Review of the Third Amended Class Action Complaint reveals that it contains a statement by Dr. Unger that allegedly supports plaintiffs' site-specific data omission allegation; since Plaintiffs put this point at issue, defendants contend that the court should have the opportunity to view this allegation in its full context by viewing the transcript. See Schnapper v. Foley, 667 F.2d 102, 106 (D.C. Cir. 1981) ("To put this allegation in context, we take judicial notice of certain indisputable facts."); Covert v. Stryker Corp., No. 1:08CV447, 2009 WL 2424559, at *1 n.2 (M.D.N.C. 2009) ("[T]he Court may take judicial notice of and consider the public records of the FDA . . . without transforming this motion into a motion for summary judgment.") (quoting Horne v. Novartis Pharm. Corp., 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008). Defendants also note that the full context contradicts plaintiffs' allegation, which is an important consideration under the PSLRA. See Plumlee v. Pfizer, Inc., No. 13-CV-00414-LHK, 2014 WL 695024 (N.D. Cal. 2014), at *4 ("However, the Court need not accept as true allegations that contradict matters properly subject to judicial notice or by exhibit or allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences.") (internal quotations and citations omitted).

B. Taking Judicial Notice

Under Federal Rule of Evidence 201, courts may judicially notice a fact that is not subject to reasonable dispute, so long as the fact is generally known within the court's territorial jurisdiction or can be accurately and readily determined from sources whose accuracy cannot

reasonably be questioned. FRE 201. Plaintiffs' challenge to judicial notice is, however, more fundamental, arguing that: the court can only take judicial notice of documents which serve as a basis for the plaintiffs' claim; that Rule 201 does not allow the court to consider what would otherwise be inadmissible hearsay simply because it was presented to a public body or found in a publically available document; that the facts such documents purport to portray are in dispute; that the inferences defendants would have this court draw from those documents in derogation of its Third Amended Complaint are without basis; and that there is no legal basis for the court to consider exhibits that were submitted with defendants' previous requests for judicial notice or defendants' summary chart.

The court concludes that while there is little doubt that the statements defendants wish the court to take notice of are contained in public documents and that they were accurately recorded by the FDA, the value or weight the court should afford any of these statements cannot be determined until such statements have been vetted through the discovery process. Likewise, plaintiffs contend that reliance on defendants' SEC filings is also troubling as it is these very filings which have led them to bring their action based on misrepresentation, false statements, and lack of full disclosure. See Maimann v. Talbott, 2010 U.S. Dist. LEXIS 142712, at *21 (C.D. Cal. Aug. 9, 2010). After considering the proposed exhibits and the arguments, the court agrees with plaintiffs that while the source of the documents is not in dispute and that the documents were presented and kept in the regular course of business of a very reliable public agency, the "facts" asserted in those documents are not only in dispute, but lie at the core of this lawsuit. Clatterbuck, 708 F.3d at 557.

Generally, when, as here, a defendant moves to dismiss a complaint under Rule 12(b)(6), courts are limited to considering the sufficiency of allegations set forth in the complaint and any “documents attached or incorporated into the complaint.” E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc., 637 F.3d 435, 448 (4th Cir. 2011); see Clatterbuck v. City of Charlottesville, 708 F.3d 549, 557 (4th Cir. 2013). As a result, consideration of extrinsic documents by a court during the pleading stage of litigation improperly converts the motion to dismiss into a motion for summary judgment. E.I. du Pont de Nemours & Co., 637 F.3d at 448. Such a conversion is inappropriate when the parties have not had an opportunity to conduct reasonable discovery. Id.; see Fed.R.Civ.P. 12(b), 12(d), and 56. Courts should therefore focus their inquiry on the sufficiency of the facts relied upon by the plaintiffs in the complaint. Am. Chiropractic Ass’n v. Trigon Healthcare, Inc., 367 F.3d 212, 234 (4th Cir. 2004).

There is, however, a narrow exception to this rule, “under which courts are permitted to consider facts and documents subject to judicial notice without converting the motion to dismiss into one for summary judgment.” Zak v. Chelsea Therapeutics Int’l, Ltd., 780 F.3d 597, 607 (4th Cir. 2015) (citing Clatterbuck, 708 F.3d at 557). Under Federal Rule of Evidence 201, courts may judicially notice a fact that is not subject to reasonable dispute, so long as the fact is generally known within the court’s territorial jurisdiction or can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned. Should the court consider such relevant facts from the public record, however, the court is required to construe them in the light most favorable to the plaintiffs. Clatterbuck, 708 F.3d at 557. Additionally, the determination of whether a fact is properly considered under this exception depends on the manner in which the court uses this information. Id. (holding that the district court improperly considered contents of a public

record as an established fact and as evidence contradicting the complaint). Put another way, consideration of a document attached to a motion to dismiss is ordinarily permitted when the document is “integral to and explicitly relied on in the complaint” and when “the plaintiffs do not challenge [the document’s] authenticity.” Am. Chiropractic Ass’n, 367 F.3d at 234 (internal quotations omitted); see Cozzarelli, 549 F.3d at 625 (where the court considered investment analyst reports attached to the defendants’ motion to dismiss because the complaint quoted from those reports and the plaintiffs did not challenge the reports’ authenticity). Here, the court agrees with plaintiffs that consideration of those documents at this stage in the litigation is premature and will decline to take judicial notice of the defendants’ Exhibits 1-7, 10, 12-17, 21, and 25-26.

C. Consideration of the Motion to Dismiss

As discussed above, the standard for pleading changes when a complaint is brought under the PSLRA, and plaintiff must adequately plead: (1) a material misrepresentation or omission by the defendant; (2) *scienter*; (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation. Stoneridge Inv. Partners, LLC, 552 U.S. at 157. Defendants argue that plaintiffs’ complaint does not survive the heightened PSLRA standard, suggesting that plaintiffs have not pleaded fraud with particularity and has failed to state a claim upon which relief may be granted.

First, defendants contend that plaintiffs have not pleaded a material misrepresentation, by either a false or misleading statement or by a material omission. Defendants note that plaintiffs’ Third Amended Complaint challenges over fifty statements made by Chelsea and its officers from September 20, 2010 to March 7, 2012, but has conceded that all of these statements are true, and thus they cannot function as material misrepresentations. Defendants also point out that the Third

Amended Complaint never alleges that defendants guaranteed approval for NORTHERA and cites repeated instances of defendants disclosing setbacks and substantial risks associated with regulatory approval.

Second, defendants argue in light of these problems, plaintiffs must rely on a theory of omission, but that they fail to state a claim because no omission is actionable. Defendants contend that the Third Amended Complaint does not explain how or why the listed omissions make the challenged statements material representations, but instead lays out long block quotes containing alleged false and misleading statements and other long block quotes with a generic paragraph listing the same omissions over and over. Defendants note that this forces them to argue every possible combination of statement and omission, even when the connections are highly attenuated. Defendants argue such failure to explain how and why the challenged statements are rendered false and misleading is sufficient to sustain a motion to dismiss. In In re First Union Corp. Sec. Litig., 128 F. Supp. 2d 871, 886 (W.D.N.C. 2001), this court held:

The plain language of the Reform Act requires that the Amended Complaint “state with particularity facts giving rise to a strong inference that the defendant [knew that a statement or omission was false or misleading].” At a minimum, this requires that:

- (1) For each alleged misstatement or omission, plaintiffs must plead specific facts concerning, for example, when each defendant or other corporate officer learned that a statement was false, how that defendant learned that the statement was false, and the particular document or other source of information from which the defendant came to know that the statement was false;¹⁴
- (2) Only “particularized” facts can be considered in determining whether the plaintiff has met the pleading burden (*i.e.* it is the particularized “facts” plaintiffs plead that must support the strong inference); and
- (3) It is not sufficient for a plaintiff to plead facts that could plausibly be consistent with innocent conduct. To survive a motion to dismiss the facts alleged must create a “strong inference” of wrongful intent.

In re First Union Corp. Sec. Litig., 128 F. Supp. 2d 871, 886 (W.D.N.C. 2001) (footnotes and

citations omitted).

Defendants also note that many of the challenged statements are not actionable because they constitute puffery and trade talk, and that stated optimism for plaintiffs' chances of approval is not fraud. Defendants also argue that plaintiffs have not shown that statements of opinion are actionable, as plaintiffs have not attempted to show that such opinions were subjectively false or lacked a basis in fact, as required by the Fourth Circuit. See Nolte v. Capital One Fin. Corp., 390 F.3d 311, 315 (4th Cir. 2004) (complaint must allege "opinion expressed was different than the opinion actually held"). Most significantly, defendants argue that no omission alleged by plaintiffs is actionable.

In total, plaintiffs allege that over fifty challenged statements were false and misleading because defendants failed to disclose the FDA's recommendation for two pivotal studies demonstrating the efficacy of NORATHERA, and that this failure to disclose the FDA's preference for two studies misled investors regarding Defendants' communications with the FDA and the strength of its NDA.

Putting aside the problems with judicial notice, defendants have come forward with a number of strong arguments why plaintiffs' Third Amended Complaint is insufficient under the PSLRA including arguments that regulatory guidance is public knowledge and presumed known by investors, Phillips v. LCI Int'l, Inc., 190 F.3d 609, 615 (4th Cir. 1999), the "why and how" the challenged statements have been rendered misleading through omission, In re Columbia Labs., Inc. Sec. Litig., 2013 U.S. Dist. LEXIS 151002, at *18-19 (D.N.J. 2013), that reasonably held opinion that is later proven wrong is not actionable, In re Medimmune, Inc. Sec. Litig., 873 F.

Supp. 953, 966-67 (D. Md. 1995), the inapplicability of fraud by hindsight, Hillson Partners Ltd. P'Ship v. Adage, Inc., 42 F.3d 204, 209 (4th Cir. 1994), the inability to plead an actionable omission when the relevant risks were disclosed to investors, Singer v. TranS1, Inc., 2015 WL 2341907, at *7-8 (E.D.N.C. 2015), and the lack of a duty to disclose recommendations which are provisional and nonbinding, Sarafin v. BioMimetic Therapeutics, Inc., 2013 WL 139521, at *18 (M.D. Tenn. 2013). While these arguments may prove meritorious at summary judgment, the court cannot conclude from the pleadings alone that plaintiffs have failed to state causes of action under Rule 12(b)(6) or 9(b), or under the PSLRA. In light of all the material now before it, the better course is to allow plaintiffs the discovery they seek as to the documents defendants contend support dismissal and deny the Motion to Dismiss without prejudice.

The court will direct that defendants answer the Third Amended Class Action Complaint within 21 days and, after issues are so joined, direct that a Pretrial Order be entered and supervised by Judge Keesler. The defendants' Motion to Dismiss Amended Class Action Complaint pursuant to Rule 9(b) and Rule 12(b)(6) (#111) will be denied without prejudice as to reasserting the substance of such motion in the form of a motion for summary judgment at the close of discovery.

While plaintiffs have survived the day, they are cautioned that defendants have made excellent points under the PSLRA. As the court has recently seen in other *major* securities class litigation that has come before it, amicable resolution of this dispute would bring with it some finality and allow the parties to get back to doing what it is they do best. After issues join, the

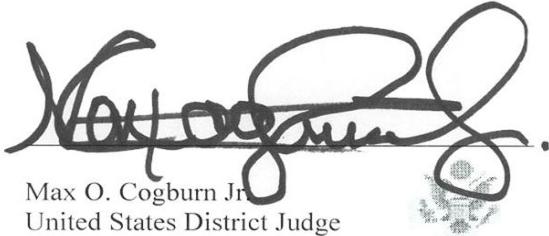
parties shall conduct an IAC, file a CIAC, and propose a Pretrial Order for consideration by Judge Keesler.

ORDER

IT IS, THEREFORE, ORDERED that defendants' Motion to Dismiss Amended Class Action Complaint pursuant to Rule 9(b) and Rule 12(b)(6) (#111) is **DENIED WITHOUT PREJUDICE** and their Request [Motion] for Judicial Notice and Notice of Incorporation by Reference (#114) is **DENIED**.

Defendants shall answer the Third Amended Class Action Complaint within 21 days and the parties shall conduct an IAC and file the required submittals within the time provided by the Local Civil Rules.

Signed: August 26, 2015



The image shows a handwritten signature in black ink, appearing to read "Max O. Cogburn Jr.". Below the signature, there is a small, faint circular stamp or seal.

Max O. Cogburn Jr.
United States District Judge